

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US06/43242

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/32 (2007.01)

USPC - 606/171

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61B 17/32 (2007.01)

USPC - 606/171

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2001/0005778 A1 (OUCHI) 28 June 2001 (28.06.2001) entire document	1-6, 11, 15, 17-18, 22 ----- 7-10, 12-14, 16, 19-21
X -- Y	US 6,142,997 A (MICHELSON) 07 November 2000 (07.11.2000) entire document	23 ----- 7-10, 12-14, 16, 19-21, 24-25
Y	US 2003/0009125 A1 (NITA et al) 09 January 2003 (09.01.2003) entire document	24-25
A	US 2005/0080441 A1 (DODGE et al) 14 April 2005 (14.04.2005) entire document	1-25
A	US 2004/0049217 A1 (ROSS et al) 11 March 2004 (11.03.2004) entire document	1-25

☐

Further documents are listed in the continuation of Box C.

☐

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

21 June 2007

Date of mailing of the international search report

18 SEP 2007

Name and mailing address of the ISA/US

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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: Derek V. Forinash
Conley Rose, P.C.
P.O. Box 3267
Houston, Texas 77253-3267

Date of mailing
(day/month/year)

18 SEP 2007

Applicant's or agent's file reference
2329-01002

FOR FURTHER ACTION

See paragraph 2 below

International application No.
PCT/US06/43242

International filing date (day/month/year)
06 November 2006

Priority date (day/month/year)
04 November 2005

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61B 17/32 (2007.01)
USPC - 606/171

Applicant **X-STEN, CORP**

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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Facsimile No. 571-273-3201

Date of completion of this opinion
21 June 2007

Authorized officer:

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**WRITTEN OPINION OF THE
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Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed
☐ filed together with the international application in electronic form
☐ furnished subsequently to this Authority for the purposes of search

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	7-10, 12-14, 16-22, 24-25	YES
	Claims	1-6, 11, 15, 23	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-25	NO
Industrial applicability (IA)	Claims	1-25	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-6, 11 and 15 lack novelty under PCT Article 33(2) as being anticipated by Ouchi (US 2001/0005778).

Regarding claim 1, Ouchi discloses a device for percutaneously excising tissue comprising: an elongate body including a first member (20) having a distal cutting end (21) and a second member (10) that slidably engages the first member, wherein the second member includes a tissue capture chamber (12) having an opening facing the first member; and wherein the first member is movable relative to the second member between an opened (Figure 16) and closed position (Figure 17), wherein the first member is disposed across the tissue capture chamber of the second member when the first member is in the closed position (see Figure 17).

Regarding claim 2, the first member and second member move substantially parallel to each other ([0003]).

Regarding claim 3, the body has a longitudinal axis and the first member (20) moves substantially parallel to the longitudinal axis relative to the second member ([0003]; Figures 16 and 17).

Regarding claim 4, the second member (10) comprises a distal cutting end (11) adjacent the distal end (21) of the second member when the first member is in the closed position (Figure 17).

Regarding claim 5, the distal end of the second member is a distal cutting end (21; [0003]).

Regarding claim 6, the first member (20) has an inner surface facing the second member (10) and an outer surface facing away from the second member and wherein the second member includes an inner surface defining the tissue capture chamber (12), an outer surface facing away from the top portion of the first member (Figure 16), and a dynamic sliding surface (forming distal tip 11) extending between the inner and outer surface of the second member and slidably engaging the inner surface of the first member (Figure 17).

Regarding claim 11, the distal cutting end of the first member comprises a beveled surface (21) extending between the inner and outer surface that forms a sharpened cutting tip (Figure 16; [0003]).

Regarding claim 15, at least a portion of the body is contoured (Figure 16).

Claims 17-18, and 22 lack an inventive step under PCT Article 33(3) as being obvious over Ouchi (US 2001/0005778).

Regarding claim 17, Ouchi discloses a method for treating tissue comprising: providing a tissue excision device comprising: a first member (20) and a second member (10) slidably engaging the first member, wherein the second member includes a cavity (12) having an opening that faces the first member (Figure 17), and wherein the first member and second member are movable relative to one another between an opened (Figure 16) and closed position (Figure 17) and wherein the first member is disposed across the cavity of the second member when the first member is in the closed position (Figure 17); positioning the tissue excision device adjacent the region of interest and opening the cavity of the device by sliding the first member relative to the second member and inserting the device into the tissue in the region of interest (Figure 16); closing the cavity of the tissue excision device by sliding the first member relative to the second member and capturing an excised tissue segment (101) within the cavity (Figure 17; [0004]). Ouchi does not disclose that the device is used to treat stenosis in the spine, but does disclose the device is suitable for use in any organ where tissue is to be collected ([0001]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method and device disclosed by Ouchi used to treat stenosis in the spine or any other organ where tissue material is to be collected and treated.

Regarding claim 18, Ouchi substantially teaches the claimed invention as applied to claim 17 above, does not specifically disclose withdrawing the device from the region of interest. However, it would have been obvious to one having ordinary skill in the art to remove the device since it is a tissue collecting device and not an implant to be permanently retained in the body.

Regarding claim 22, Ouchi substantially teaches the claimed invention as applied to claim 17 above, but does not disclose the region of interest and excised tissue is a portion of the patient's ligamentum flavum, but does disclose the device is suitable for use in any organ where tissue is to be collected ([0001]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method and device disclosed by Ouchi wherein the region of interest is the ligamentum flavum or any other organ where tissue material is to be collected and treated.

Claims 7-10, 12-14, 16, and 19-21 lack an inventive step under PCT Article 33(3) as being obvious over Ouchi (US 2001/0005778) in view of Michelson (US 6,142,997).

Regarding claim 7, Ouchi substantially discloses the claimed invention as applied to claim 1 above, but does not disclose the outer surface of the first member is disposed at a radius R1 that is substantially the same as the radius R2 of the outer surface of the second member. Michelson however teaches a cutting device having first (850) and second (814) members wherein the outer surface of the first member is disposed at a radius R1 that is substantially the same as the radius R2 of the outer surface of the second member (see Figure 29) to facilitate passage of the device through the skin or body while providing a good seal against leakage (column 23, lines 43-50). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device disclosed by Ouchi wherein the radius of outer surface of the first and second members are the same, as taught by Michelson, to facilitate passage of the device through the skin or body while providing a good seal against leakage.

Continued in Supplemental Box

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box V

Regarding claim 8, Ouchi further discloses the inner surface of the second member (10) defining the tissue cavity chamber is located at a radius R3 that is less than the radius of the outer surface R2 of the second member (see Figure 14).

Regarding claim 9, Ouchi further discloses a sleeve (130) having an inner surface defining a bore, wherein the body is at least partially disposed in the bore (see Figure 19).

Regarding claim 10, the outer surface of the first and second members slidably engage the inner surface of the sleeve (Figure 19; [0074]).

Regarding claim 12, Ouchi does not disclose the sliding surface of the second member (10) comprises a recess that mates with a projection extending from the first member (10). Michelson however teaches a cutting device wherein the sliding surface of the second member (814) comprises a recess that mates with a projection extending from the first member (850; see Figure 29) to facilitate passage of the device through the skin or body while providing a good seal against leakage (column 23, lines 43-50). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device disclosed by Ouchi wherein having a recess and a mating projection, as taught by Michelson, to facilitate passage of the device through the skin or body while providing a good seal against leakage.

Regarding claim 13, Ouchi does not disclose a rail system between the first and second members to restrict movement of the members to directions substantially parallel to the axis of the body. Michelson however teaches a rail system between first and second members (50 and 14) to restrict movement of the members to directions substantially parallel to the body (Figure 6; column 10, lines 55-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device disclosed by Ouchi having a rail system, as taught by Michelson, to facilitate and restrict movement between the first and second members.

Regarding claim 14, Ouchi in view of Michelson substantially teaches the claimed invention as applied to claims 1 and 13 above, but does not teach the distal end of the tissue retrieval device has a barb. Michelson does disclose a stylet or any other suitable instrument may be used for removing the pieces of tissue from the tissue chamber (88; column 13, lines 14-21). It would have been an obvious matter of design choice to one having ordinary skill in the art at the time the invention was made to provide the device taught by Ouchi in view of Michelson wherein the tissue retrieval device has a barb or any other shape that would facilitate removal of the tissue fragments from the storage chamber.

Regarding claim 16, Ouchi substantially discloses the claimed invention as applied to claim 1 above, but does not disclose a tissue ejector including a plunger slidably received in the tissue capture chamber of the second member. Michelson however teaches a tissue ejector comprising a plunger slidably received within the tissue capture chamber (88) for removing tissue fragments from the chamber (column 13, lines 14-31). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device disclosed by Ouchi including a tissue ejector, as taught by Michelson, to facilitate removal of the tissue fragments from the storage chamber.

Regarding claim 19, Ouchi substantially teaches the claimed invention as applied to claim 17 above, but does not disclose opening the cavity and emptying the tissue from the cavity using a plunger slidably disposed within the cavity of the second member. Michelson however teaches opening the cavity and using a plunger (stylet) slidably disposed within the cavity (88) to remove tissue fragments from the device (column 13, lines 14-31). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method and device disclosed by Ouchi including a plunger, as taught by Michelson, to facilitate removal of the tissue fragments from the storage chamber.

Regarding claims 20 and 21, Ouchi substantially teaches the claimed invention as applied to claim 17 above, but does not disclose a tissue retrieval device slidably disposed in the tissue capture chamber of the second member for retrieving and removing excised tissue from the cavity. Michelson however teaches a tissue retrieval device (stylet) disposed within the tissue capture chamber (88) for removing tissue fragments from the chamber (column 13, lines 14-31). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method and device disclosed by Ouchi including a tissue retriever, as taught by Michelson, to facilitate removal of the tissue fragments from the storage chamber.

Claims 23 lacks novelty under PCT Article 33(2) as being anticipated by Michelson (US 6,142,997).

Regarding claim 23, Michelson discloses a lot capable of performing a procedure on a spine (column 1, lines 21-28 and 40-63) comprising: a tissue excision device comprising:

a first moveable member (14); a second moveable member (50) including a tissue capture chamber (88) having an opening facing the first moveable member wherein the second moveable member slidably engages the first member (column 10, lines 55-67); wherein the first member is slidable between a first closed position and a second open position (column 4, lines 43-55; column 5, lines 24-35); and a tissue retrieval device (stylet; column 13, lines 15-30).

Claims 24 and 25 lack an inventive step under PCT Article 33(3) as being obvious over Michelson (US 6,142,997) in view of Nita et al (US 2003/0009125).

Regarding claim 24, Michelson substantially discloses the claimed invention as applied to claim 23 above, but does not disclose a contrast medium adapted to be inserted into the epidural space by an insertion member and expanded to as to compress a portion of the thecal sac and provide a safety zone. Nita et al however teaches a device for removing tissue comprising a contrast medium inserted by an insertion member (26a) to provide radiographic visualization to the area of treatment ([0090]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device disclosed by Michelson including a contrast medium, as taught by Nita et al, to provide radiographic visualization to the area of treatment.

Continued in Next Supplemental Box

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Previous Supplemental Box

Regarding claim 25, Michelson substantially discloses the claimed invention as applied to claim 23 above. Michelson does not disclose the tissue retrieval device has a barb on the distal end, but does disclose the use of a stylet or other instrument suitable for the removal of the pieces (column 13, lines 22-31). It would have been an obvious matter or design choice to one having ordinary skill in the art at the time the invention was made to provide the device disclosed by Michelson wherein the retrieval device has a barb or any other shaped distal end that would facilitate removal of the cut pieces from the storage chamber of the device.

Claims 1-25 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.